UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

DEBORAH DELAVERN,

Plaintiff,

Hon. Hugh B. Scott

v.

10CV116S

Report
&
Recommendation

BOSTON SCIENTIFIC CORPORATION,

Defendant.

This matter has been referred to the undersigned pursuant to 28 U.S.C. § 636(b)(1)(C) (Docket No. 13 (Order referring defendant's motion for summary judgment); see also Docket No. 7 (initial referral Order)). The instant matter before the Court is defendant's motion summary judgment (Docket No. 11[1]). Responses to this motion were due by April 16, 2010, and any reply by April 30, 2010, and the motion was deemed submitted (without oral argument) on April 30, 2010 (Docket No. 14).

[1]In support of its motion, defendant submits its Statement of Undisputed Material Facts, with Appendix of exhibits, the Memorandum of Law, Docket No. 11; and its Reply Memorandum, Docket No. 15.

In opposition, plaintiff submits her Memorandum of Law, Docket No. 15.

BACKGROUND

This is a removed diversity[2] action arising from plaintiff's claim of "severe and permanent injuries" as a result of the implantation of a TAXUS® Stent (hereinafter the "Stent") (Docket No. 1, Notice of Removal ¶¶ 3-8). The Stent is a Food and Drug Administration ("FDA") approved medical device used to treat coronary artery disease, "particularly stenosis (narrowing) of coronary arteries" (Docket No. 11, Def. Memo. at 1). Defendant designed, manufactured, and sold the Stent (Docket No. 11, Def. Statement ¶ 1). Plaintiff alleges that she was injured by the Stent implanted in her, asserting state law claims for the design, making, manufacture, inspection, testing, distribution, marketing, and/or selling of the Stent (Docket No. 11, Def. Memo. at 1).

On September 25, 2009, plaintiff filed this Complaint in New York State Supreme Court and served it on defendant on January 15, 2010 (Docket No. 1, Notice of Removal ¶ 9, Ex. A, state Summons and Complaint). Defendant filed its Notice of Removal on February 11, 2010 (Docket No. 1), and filed its Answer the next day (Docket No. 6). Just prior to the Scheduling Conference for this matter (cf. Docket No. 10), defendant filed the present summary judgment motion (Docket No. 11). As a result the Scheduling Conference was canceled until this motion was decided (Docket No. 12).

Summary Judgment Motion

Defendant contends in its motion that the federal Medical Device Amendments of 1976, 21 U.S.C. § 360k(a) ("MDA"); Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008), preempts

[2]Plaintiff is a New York citizen and defendant is a Delaware corporation with its principal place of business in Massachusetts, Docket No. 1, Notice of Removal ¶¶ 3, 4, Ex. A, Summons, State Compl.

plaintiff's state law claims against defendant (Docket No. 11, Def. Memo. at 1). The Supreme Court in Riegel held that state tort law is preempted by the MDA where state law imposes requirements to FDA-approved medical devices that are "different from, or in addition to" federal requirements, Riegel, supra, 552 U.S. at 322; 21 U.S.C. § 360k(a)(1) (id.). Defendant contends that the Stent here was granted premarket approval (or "PMA") by the FDA and defendant had subsequently submitted, and the FDA approved, 70 supplements to the Stent and 5 updates to the Stent's directions for use (Docket No. 11, Def. Statement of Facts ¶¶ 2-4, Exs. C, K, D-H, I; Docket No. 11, Def. Memo. at 4-5 & nn.4-10). Citing numerous cases since Riegel (Docket No. 11, Def. Memo. at 2 n.2), defendant concludes that plaintiff's state law tort claims here regarding use of the Stent would impose state law requirements that differ from or additional to federal requirements and should be dismissed (id. at 2-3).

Plaintiff responds that defendant's motion is really one seeking dismissal of the action under Rule 12 and, as such, should be denied since the Complaint plead causes of action (Docket No. 15, Pl. Memo.). Alternatively, she seeks leave to amend her New York State Complaint to plead the specifics of her claims (id. at 4). As for preemption of her express warranty claims, plaintiff argues that Riegel did not find that such claims were preempted under the MDA (id.).

Initially, defendant argued that Riegel did not address whether the MDA preempted express warranty claims (Docket No. 11, Def. Memo. at 13). In reply, defendant contends that plaintiff here really asserts implied warranty claims and (whether termed expressed or implied) her warranty claims are preempted by the MDA because these claims "challenge[] the safety and effectiveness of the TAXUS Stent®" (Docket No. 16, Def. Reply Memo. at 6-7; Docket No. 11, Def. Memo. at 13). As for her other claims, defendant argues that she has not asserted parallel

claims and she does not allege any violation of FDA regulations (Docket No. 16, Def. Reply Memo. at 2-4). Further, any claims that defendant violated FDA regulations is impliedly preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 337; see Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001) (id. at 4).

DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate only if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Ford v. Reynolds, 316 F.3d 351, 354 (2d Cir. 2003); Fed. R. Civ. P. 56(c). The party seeking summary judgment has the burden to demonstrate that no genuine issue of material fact exists. In determining whether a genuine issue of material fact exists, a court must examine the evidence in the light most favorable to, and draw all inferences in favor of, the non-movant. Ford, supra, 316 F.3d at 354. "A dispute regarding a material fact is genuine 'if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.' " Lazard Freres & Co. v. Protective Life Ins. Co., 108 F.3d 1531, 1535 (2d Cir.) (quoting Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986)), cert. denied, 522 U.S. 864 (1997). While the moving party must demonstrate the absence of any genuine factual dispute, Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986), the party against whom summary judgment is sought, however, "must do more than simply show that there is some metaphysical doubt as to the material facts. . . . [T]he nonmoving party must come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986) (emphasis

in original removed); McCarthy v. American Intern. Group, Inc., 283 F.3d 121, 124 (2d Cir. 2002); Marvel Characters v. Simon, 310 F.3d 280, 285-86 (2d Cir. 2002).

The Local Civil Rules of this Court require that movant and opponent each submit "a separate, short, and concise" statement of material facts, and if movant fails to submit such a statement it may be grounds for denying the motion, W.D.N.Y. Loc. Civ. R. 56.1(a), (b). The movant is to submit facts in which there is no genuine issue, id. R. 56.1(a), while the opponent submits a statement of material facts as to which it is contended that there exists a genuine issue to be tried, id. R. 56.1(b). "Each statement of material fact by a movant or opponent must be followed by citation to evidence which would be admissible, as required by Federal Rule of Civil Procedure 56(e)," with citations identifying "with specificity" the relevant page or paragraph of the cited authority, id. R. 56.1(d). All material facts stated in movant's statement that are not controverted by opponent's counter-statement shall be deemed admitted, id. R. 56.1(c). The purpose of these statements, and the appendix of supporting evidence, id. R. 56.1(d), is to summarize and highlight for the Court the material factual issues, the authority in the evidentiary record for the purported facts, and whether the parties believe they are in dispute.

II. Whether to Treat Defendant's Motion as One to Dismiss

Initially, plaintiff contends that defendant's motion should be treated as one for dismissal under Federal Rule of Civil Procedure 12(b) and the Complaint construed under Rule 12 (Docket No. 15, Pl. Memo. at 2). This may explain why plaintiff did not file a counterstatement of facts. Although she argues that no discovery has been conducted here (cf. id.), plaintiff is not seeking denial of defendant's summary judgment motion on the grounds of her inability to present facts essential for her response, cf. Fed. R. Civ. P. 56(f).

Defendant, however, filed its Answer (Docket No. 6) rather than file a Rule 12(b)(6) motion to dismiss and submitted materials beyond the pleadings in support of its present motion. Although the Federal Rules provide for converting a motion to dismiss into one seeking summary judgment where additional facts are presented beyond the pleadings, Fed. R. Civ. P. 12(d), there is no reverse procedure for considering a so-called summary judgment motion as one merely seeking dismissal under Rule 12. Under the 2009 amendments to Rule 56, a motion for summary judgment may be made "at any time" up to thirty days after the close of discovery or as provided by in local rules or court Order, Fed. R. Civ. P. 56(c)(1). This Court's Local Civil Rules does not restrict when a party can move for summary judgment, cf. W.D.N.Y. Local Civ. R. 7.1, 56.1 (summary judgment statement of material facts requirement). There is no Scheduling Order issued here and any such Order would set a deadline for dispositive motions rather than the earliest date for such a motion. Therefore, plaintiff's argument to consider (and thus reject) defendant's motion as one for summary judgment should be **declined**. Next, the Court discusses the merits of defendant's summary judgment motion and applies that rule's standard for testing whether defendant has established (a) the non-existence of material issues of fact and (b) entitlement to judgment as a matter of law.

III. Federal Preemption of State Tort Claims

As for the merits, defendant argues that the MDA preempts plaintiff's state law claims as being different from or in addition to federal requirements. Plaintiff replies that the MDA did not preempt "parallel" claims, see Riegel, supra, 552 U.S. at 330 (allowing state to provide damages for claims premised on violation of FDA regulations) (Docket No. 15, Pl. Memo. at 3) and her state law claims may be such parallel claims (id.), although she does not argue how her

claims are parallel to FDA regulations. She also contends that express warranty claims were not preempted by Riegel (id. at 3-4). But plaintiff couched this argument in terms of the sufficiency of her pleading (as if for a motion to dismiss) rather than whether defendant established the absence of material issues of fact or entitlement to judgment as a matter of law under Rule 56. Furthermore, since plaintiff has not submitted her statement of material facts, those stated by defendant are deemed admitted.

A. Plaintiff's Claims

The first cause of action alleges negligence in defendant's design, making, manufacture, inspection, testing, distribution, marketing and/or sale of the Stent (Docket No. 1, Notice of Removal, Ex. A, State Compl. ¶ 5), while the third cause of action alleges strict product liability claim (id. ¶¶ 9-11). Although originally plead as a state court action, there is no indication here of any parallel claim or a claim for defendant violating FDA regulations. These claims are different from and in addition to such FDA regulatory or MDA requirements; as a result, these state law claims are preempted under federal law. Thus, defendant's summary judgment motion should be **granted** and these claims **dismissed**.

B. Plaintiff's Warranty Claims

In her second cause of action, plaintiff alleges that she was injured due to breach of express and implied warranties that the Stent was reasonably fit for use by plaintiff (Docket No. 1, Notice of Removal, Ex. A, State Compl. ¶ 7). The implied warranty claims also are preempted by federal law under the analysis presented above and judgment dismissing those claims **should be granted**. The remaining issue is whether such express warranty claims are preempted by the MDA.

An express warranty claim is premised on safety and effectiveness of the device, areas under federal jurisdiction under the MDA. As another court held in a multidistrict litigation involving a different medical device, In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009), such express warranty claims are preempted by federal law like implied warranty claims; see also Lake v. Kardjian, 22 Misc.3d 960, 963, 874 N.Y.S.2d 751, 752 (Sup. Ct. Madison County 2008) (express warranty claim based on FDA approved statements in product labeling preempted by the MDA).

Plaintiff fails to set forth the terms of the express warranty claimed here that defendant violated (Docket No. 11, Def. Memo. at 13-14; cf. Docket No. 1, Notice of Removal, Ex. A, State Compl. ¶ 7), e.g., Davis v. New York City Hous. Auth., 246 A.D.2d 575, 576, 668 N.Y.S.2d 391, 393 (2d Dep't 1998) (upholding dismissal of express warranty claim where plaintiffs failed to set forth terms of the warranty upon which they relied). So it is unclear whether the express warranty stems from the labeling approved for the Stent by the FDA or from some other source.

Defendant responds that plaintiff has not described any proposed amendment, that her assertions are "devoid of 'further factual enhancement'" (Docket No. 16, Def. Reply Memo. at 8, quoting Ashcroft v. Iqbal, 556 U.S. ___, 129 S.Ct. 1937, 1949 (2007), quoting in turn Bell Atl. v. Twombly, 550 U.S. 544, 557 (2007)). As defendant notes (id. at 7 n.3), any amendment is governed by Federal Rule of Civil Procedure 15(a), that the proposed amendment not be futile. Where leave to amend a Complaint is to be freely given when justice requires, and granting such leave is within the sound discretion of the Court, Foman v. Davis, 371 U.S. 178, 182 (1962); Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 330 (1971), if amendment would

be futile (that is, not survive a dispositive motion if allowed), leave to amend would not be given, cf. Foman, supra, 371 U.S. at 182. But amendment here as suggested by plaintiff would be futile.

CONCLUSION

Based upon the above, it is recommended that defendant's motion for summary judgment (Docket No. 11) be **granted**.

Pursuant to 28 U.S.C. § 636(b)(1), it is hereby ordered that this Report & Recommendation be filed with the Clerk of the Court and that the Clerk shall send a copy of the Report & Recommendation to all parties.

ANY OBJECTIONS to this Report & Recommendation must be filed with the Clerk of this Court within fourteen (14) days after receipt of a copy of this Report & Recommendation in accordance with 28 U.S.C. § 636(b)(1), Fed. R. Civ. P. 72(b) (effective December 1, 2009) and W.D.N.Y. Local Civil Rule 72.3(a).

FAILURE TO FILE OBJECTIONS TO THIS REPORT & RECOMMENDATION WITHIN THE SPECIFIED TIME OR TO REQUEST AN EXTENSION OF SUCH TIME WAIVES THE RIGHT TO APPEAL ANY SUBSEQUENT DISTRICT COURT'S ORDER ADOPTING THE RECOMMENDATIONS CONTAINED HEREIN. Thomas v. Arn, 474 U.S. 140 (1985); F.D.I.C. v. Hillcrest Associates, 66 F.3d 566 (2d Cir. 1995); Wesolak v. Canadair Ltd., 838 F.2d 55 (2d Cir. 1988).

The District Court on de novo review will ordinarily refuse to consider arguments, case law and/or evidentiary material which could have been, but was not, presented to the Magistrate

Judge in the first instance. See Patterson-Leitch Co. Inc. v. Massachusetts Municipal Wholesale Electric Co., 840 F.2d 985 (1st Cir. 1988).

Finally, the parties are reminded that, pursuant to W.D.N.Y. Local Civil Rule 72.3(a)(3), "written objections shall specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for such objection and shall be supported by legal authority." **Failure to comply with the provisions of Rule 72.3(a)(3) may result in the District Court's refusal to consider the objection.**

SO ORDERED.

/s/ Hugh B. Scott
Hon. Hugh B. Scott
United States Magistrate Judge

Dated: Buffalo, New York
May 24, 2010